

## **REMARKS**

Reconsideration of the present application in view of the following remarks is respectfully requested. The application includes claims 72-135 and 249-361, pending and under consideration. No amendments to the claims are being made in this Response.

In the outstanding Action, claims 72-135 and 249-361 were pending, and claims 72-134, 249-268 and 292-361 stand rejected. In addition, the "amendment filed 12/17/04 is objected to under 35 U.S.C. 132" on the grounds that it introduces new matter into the disclosure.

As one preliminary matter, Applicant would draw the Examiner's attention to the fact that claims 135 and 269-291 are pending in the present application; however these claims are not identified on the Office Action Summary sheet enclosed with the Action as being pending or as being rejected, nor are these claims mentioned in the body of the Office Action. Applicant believes that claims 135 and 269-291 are in condition for allowance; and because the Action does not assert any grounds for rejecting same, Applicant respectfully requests an indication that these claims are allowed.

As another preliminary matter, Applicants would draw the Examiner's attention to the fact that a Petition for Withdrawal of Finality of Premature Final Rejection is being submitted in this case simultaneously with this Response. For the reasons stated therein and discussed below, it is believe that the holding of finality asserted in the outstanding Office Action is premature. Applicants respectfully request withdrawal of the holding of finality and reconsideration of the present application without the limitations of finality.

Applicants acknowledge and thank the Examiner for the indication at Page 6 of the outstanding Action that the 112 rejections directed to the wording "...said upper and lower portions being non-arcuate along at least a portion of the length of said implant..." has been withdrawn.

The remaining issues in the present case are addressed below.

**Remarks Regarding Objection Under 35 U.S.C. §132 and a Rejection Under 35 U.S.C. §112, first paragraph**

The outstanding Office Action maintains a new matter objection, and an accompanying rejection under Section 112, first paragraph, with regard to the following language in the specification:

“Each of dowels 500 are illustrated as having a width less than approximately one-half of the width of the adjacent vertebral body.”

and the following language in the claims:

“...said maximum width of said implant being less than approximately one-half of the width of the adjacent vertebral bodies...”

Specifically, the Action states that this subject matter is added material that is not supported by the original disclosure. In support of the objection and rejection, the Examiner asserts that “the MPEP states that the drawings are not to scale and one of ordinary skill in the art would not make the assumption of measurements as each implant may be placed in an anatomy of varied proportion for example the claims do not limit the implants from only being utilized in human patients.” (Office Action, Page 6).

In traversal of the new matter objection and rejection, Applicants submit that the identified subject matter is fully supported by the original disclosure and does not require a person of ordinary skill in the art to make any assumptions regarding measurements from the drawings. The identified subject matter would have been understood by a person of ordinary skill in the art at the time of the application to be clearly described in the specification, and does not rely upon proportions depicted in the drawings.

MPEP §2125 states that, “the description of the article pictured can be relied on, in combination with the drawings, for what they would reasonably teach one of ordinary skill in the art.” (emphasis added) (citation omitted). In the record of the present case, Applicants have previously identified descriptions in the specification that, together with the drawings, disclose the claimed subject matter. Such descriptions, and also additional statements in the specification, are identified and discussed below.

As discussed in Applicants' prior responses in the record of this case, the identified claims are directed to an "interbody spinal implant." The term "interbody" is understood by skilled artisans to mean located between the bodies of two adjacent vertebra. Paragraph 66 of the published version of the present application (Application Publication No. 2004/0073309) includes the following statement regarding the embodiment depicted in Fig. 6: "Bilateral placement of dowels 500 is preferred as shown in FIG. 6." The term "bilateral" is well understood by skilled artisans to mean located on two sides of a central axis. More specifically, in terms of interbody spinal implants, the term "bilateral" is understood to mean located on two sides of the central axis of the spinal column. Moreover, dowels 500 depicted in Fig. 6 do not overlap one another or cross the central axis of the vertebrae. Therefore, Fig. 6, which depicts an embodiment of the application involving bilateral placement of two dowels for operation as an interbody spinal implant, would be clearly understood by a person of ordinary skill in the art to be characterized by each dowel having a width less than approximately one-half of the width of the adjacent vertebral body. This is the case irrespective of the sizes of the vertebral bodies, or the size proportions between the vertebral bodies and the spacers. Otherwise, the dowels could not be both bilateral and positioned between vertebral bodies.

Additional disclosures in the specification also support the claim language directed to implants having a "maximum width ... less than approximately one-half of the width of the adjacent vertebral bodies...." Examples are set forth below. The following quotation is taken from paragraph 62 of the published application:

(1) "These spacers are advantageous for maximum exposure of vertebral tissue to osteogenic material within the chamber and allow close placement of a pair of spacers within the intervertebral space."

It is apparent from the above statement that the specification discloses embodiments in which the two spacers positioned "within the intervertebral space" do not overlap one another (i.e., they are simply placed close to one another). This disclosure is also reinforced by the following statement at paragraph 69 of the published application:

(2) “Because the [insertion] tool can be placed within the channel during implantation, two spacers of this invention can be placed very closely together within the intervertebral space as shown in FIGS. 6 and 8.”

In addition to the clear support in the specification of embodiments in which two non-overlapping spacers are placed within the intervertebral space, the following statement from paragraph 67 of the published application clearly discloses to a person of ordinary skill in the art that the two spacers are positioned on opposite sides of the center of the intervertebral space:

(3) “As shown in Fig. 8, two open spacers 500' can be implanted with the mouths 525' facing to the center of the intervertebral space.” (emphasis added)

In view of the above disclosures, it is clear that the specification contemplates placement of two spacers within the intervertebral space and on opposite sides of the center of the intervertebral space. It is therefore clear that this embodiment must include a pair of spacers that are each less than approximately one-half the width of the adjacent vertebral bodies, which define the intervertebral space.

Applicants acknowledge the statement in the Action that, “The drawings are just mere examples and could for instance to [sic] manipulated to fit any variety of situations.” However, Applicants submit that the disclosure in the present specification, including the descriptions and the drawings, clearly describes the embodiment claimed. Applicants would again note that the proper inquiry under Section 112, first paragraph, is whether the specification describes the identified subject matter, not whether alternative embodiments might exist that differ from an exemplary embodiment specifically shown and described in the specification and recited in a given claim. A person skilled in the art at the time the application was filed would have understood, based upon the drawings and the accompanying descriptions, that each of the embodiments depicted in Figs. 6, 8 and 9 include two spacers that each has a width less than approximately one-half of the width of the adjacent vertebral body.

In view of the above, Applicant submits that support for the identified statement is clearly present in the application as filed, and does not require a person of ordinary skill in the art to derive any measurements or proportions from a drawing. Applicant therefore respectfully requests withdrawal of the objection to the specification under 35 U.S.C. §132 and the rejection of claims under 35 U.S.C. §112, first paragraph.

**Remarks Regarding Rejection Under 35 U.S.C. §102**

In the outstanding Action, claims 72, 91 and 111 are rejected under 35 U.S.C. 102(e) as being anticipated by Pafford et al. 6,371,988.

Applicants would first draw the Examiner's attention to the fact that this same rejection was asserted early in the prosecution of the present case (See Office Action dated August 11, 2004 and Office Action dated March 14, 2005); however, the rejection was overcome by Applicants arguments and was not asserted in subsequent substantive Office Actions. Applicants traverse this rejection again for the same reasons that the rejection was traversed previously. The prior arguments are reiterated below, and Applicants submit that the rejection is overcome for the stated reasons. Moreover, Applicants submit that the holding of finality asserted in the outstanding Office Action is improper because this rejection of claims 72, 91 and 111 is properly considered to be a new grounds for rejection (i.e., was not asserted in the preceding Office Action) and was not necessitated by any amendment. Applicants are submitting a Petition for Withdrawal of Finality of Premature Final Rejection under separate cover on today's date that addresses this more fully, and Applicants respectfully request that the holding of finality asserted in the outstanding Action be withdrawn. If the Examiner continues to maintain any objection or rejection, Applicants request that the Examiner withdraw the holding finality asserted in the outstanding Action and issue another Office Action taking note of the Applicants' arguments and answering the substance of them.

Applicants continue to believe that the previously-submitted arguments support the patentability of pending claims 72, 91 and 111, and respectfully requests an indication that each of these claims is in condition for allowance. For the convenience of the Examiner,

Applicants have below inserted a copy of the arguments submitted on September 14, 2005, in response to the prior Office Action dated March 14, 2005.

**Reiteration of Prior Arguments Regarding Rejection of Claims 72, 91 and 111 Under Section 102(e)**

Claims 72, 91 and 111 were rejected under 35 U.S.C. §102(e) as being anticipated by U.S. Patent No. 6,371,988 to Pafford et al. (hereafter “the ‘988 patent”). The Applicant notes that independent claim 134 was not rejected under 35 U.S.C. §102(e).

It is well established that “an invention is anticipated if the same device, including all the claim limitations, is shown in a single prior art reference. Every element of the claimed invention must be literally present, arranged as in the claim.” Richardson v. Suzuki Motor Co. Ltd., 9 USPQ.2d 1913, 1920 (Fed. Cir. 1989).

Paragraph 6 of the Office Action asserts that the ‘988 patent discloses an implant 40 having opposed upper and lower portions that are non-arcuate along at least a portion of the length of the implant. The non-arcuate upper portion is asserted to constitute the beveled surface (shown in Figures 47 and 48) and the non-arcuate lower portion is asserted to constitute the crest 44 of the tooth 43 (shown in Figure 8). Albeit that the ‘988 patent discloses that “the crest 44 of each tooth 43 is flat” (column 7, line 65), this description appears to be referring to the appearance of the crest 44 in axial cross-section (as shown in Figure 8) wherein the crest 44 may be considered “flat” in a circumferential sense (i.e., in that the crest 44 extending circumferentially about the implant does not have a pointed configuration as is typically the case with bone threads). However, such a “flat” crest 44 extending along the circumference of the implant would not be flattened along the length of the implant. In other words, when viewed from either end of the implant (or via a transverse cross section), the crest 44 would still have a circular or arcuate configuration. Accordingly, the “flat” crest 44 described in the ‘988 patent specification would not define upper and lower portions that are flat or non-arcuate along the length of the implant.

Moreover, the beveled surface shown in Figures 47 and 48 is referred to in the Office Action as comprising a non-arcuate upper portion. However, the Applicant respectfully disagrees with this assertion in that the beveled surface does not comprise an upper portion of

the implant “to contact and support” an adjacent vertebral body, as recited in independent claims 72, 91, 111 and 134. Specifically, the opening or chamber 25 extending through the implant (as shown in Figures 7, 47 and 48) contains an osteogenic composition and opens onto the upper and lower surfaces of the implant to promote bone growth from the endplates of the respective vertebral bodies and into the chamber 25. (See column 7, lines 50-56). Thus, one of ordinary skill in the art would understand that when the implants are positioned in the disc space, the chamber 25 opens onto the upper and lower surfaces of the implant adjacent the respective vertebral bodies. As a result, the portions of the implant that define the openings of the chamber 25 correspond to the “upper and lower portions” of the implant, and do not correspond to the portion of the implant defining the beveled surface. Indeed, the beveled surface is positioned along lateral or side portions of the implant, which would correspond to the interior or exterior facing side of the implant recited in independent claims 72, 91, 111 and 134. Accordingly, even assuming that the beveled surface comprises a non-arcuate portion of the implant, the beveled surface does not comprise an upper or lower portion of the implant.

In addition to the above-discussed reasons, further reasons support the patentability of independent claims 72, 91, 111 and 134 over the ‘988 patent. For example, independent claims 72 and 134 each recite that the implant is manufactured from a bone ring obtained from a major long bone having a medullary canal, with “said interior side of said implant including at least a portion of the medullary canal so that when said implant is placed side by side with another implant having an interior side including at least a portion of a medullary canal a passage is formed”, with the passage adapted to hold bone growth promoting material to permit bone growth through the common passage formed between the implants. (Emphasis added). This configuration is clearly illustrated in Figure 6 of the subject application wherein the interior facing sides 535 include at least a portion of the medullary canal so as to define facing chambers 530 of the bilaterally positioned implants 500 to form an elongated compartment 540 that can be filled with an osteogenic composition M. (See paragraph 66).

However, as shown in Figure 24 of the ‘988 patent, although the implants are positioned side-by-side in a bilateral arrangement, the interior facing sides of the implants (i.e., the sides of the implants which face one another) clearly do not include at least a portion

of a medullary canal, as recited in independent claims 72 and 134. Instead, the chambers 25 extend through the mid-portion of the implants, and do not intersect the interior facing sides of the implants. Since the interior sides of the implants do not include “at least a portion of the medullary canal”, the ‘988 patent does not disclose each and every feature recited in independent claims 72 and 134. Accordingly, the ‘988 patent does not anticipate independent claims 72 and 134. Moreover, the chambers 25 extending through the implants illustrated in Figure 24 of the ‘988 patent do not form a common passage that is adapted to hold bone growth promoting material. To the contrary, the chambers 25 form separate and discrete passages extending through the implants. Accordingly, for at least these reasons, the Applicant respectfully requests withdrawal of the rejection of independent claims 72 and 134 as being anticipated by the ‘988 patent.

Additionally, independent claims 91 and 111 each recite that the implant is manufactured from a bone composite material with “said interior side of said implant including a recess so that when said implant is placed side by side with another implant having an interior side including a recess a passage is formed”, with the passage adapted to hold bone growth promoting material to permit bone growth through the common passage formed between the implants. (Emphasis added). This configuration is also clearly illustrated in Figure 6 of the subject application wherein the interior facing sides 535 of the implants 500 each include a recess, and with the opposing recesses forming a common passage adapted to hold bone growth promoting.

However, as discussed above with regard to independent claims 72 and 134, although the ‘988 patent discloses implants that are positioned side-by-side in a bilateral arrangement, the interior facing sides of the implants clearly do not include recesses which form a passage to hold bone growth promoting material, as recited in independent claims 91 and 111. Instead, the chambers 25 extend through the mid-portion of the implants, and do not intersect the interior facing sides of the implants to form a recess. Since the ‘988 patent does not disclose each and every feature recited in independent claims 91 and 111, the ‘988 patent does not anticipate independent claims 91 and 111. Accordingly, for at least these reasons,



the Applicant respectfully requests withdrawal of the rejection of independent claims 91 and 11 as being anticipated by the '988 patent.

**Remarks Regarding Rejection Under 35 U.S.C. §103**

While it is not entirely clear in the outstanding Action, it appears that the Action maintains the prior rejection of claims 72-90, 134 and 135 under 35 U.S.C. § 102(e) as being anticipated by U.S. Patent No. 6,258,125 to Paul et al. (hereafter, "the '125 patent") and the prior rejection of claims 91-133 under 35 U.S.C. § 103(a) as being unpatentable over the '125 patent in view of U.S. Patent No. 6,530,955 to Boyle et al. (hereafter "the '955 patent"). The only statement in the Action regarding these references is found at the bottom of Page 6, as follows: "With regards to the art rejection of patent '125, ;955 applicants, [sic] applicant is not entitled to its claim of priority due to the new matter rejections as mentioned supra."

In reply, Applicants submit that the present application is entitled to its claim of priority and that the '125 and '955 patent references do not qualify as prior art. The new matter objection and rejection asserted in the outstanding Action are overcome for the reasons set forth above. Upon withdrawal of the new matter objection and rejection and reinstatement of the claim of priority, Applicants submit that neither of the references asserted in the Action qualifies as prior art. In this regard, Applicant would draw the Examiner's attention to the follow items of information:

- (1) the '125 patent was filed on July 30, 1999, and claims priority to a provisional patent application filed August 3, 1998;
- (2) the '955 patent was filed on May 18, 2001 and is a divisional of a patent application filed June 8, 1999; and
- (3) the present application is a continuation application that claims priority to a string of prior patent applications in a line of cases extending back to a parent application filed June 3, 1997 (U.S. Patent Application Serial No. 08/867,963).

In view of the above, the pending claims of the present application are entitled to an effective filing date at least as early as June 3, 1997, for purposes of determining qualification of references as prior art. Neither the '125 patent nor the provisional patent application to which it claims priority was filed before June 3, 1997, and the '125 patent does

not qualify as prior art to the present application under 35 U.S.C. § 102(e). Similarly, neither the '955 patent nor the prior patent application to which it claims priority was filed before June 3, 1997, and the '955 patent likewise does not qualify as prior art to the present application under 35 U.S.C. § 102(e).

Consequently, Applicant respectfully requests withdraw of the rejection of claims 72-90, 134 and 135 under 35 U.S.C. § 102(e) as being anticipated by the '125 patent and the rejection of claims 91-133 under 35 U.S.C. § 103(a) as being unpatentable over the '125 patent in view of the '955 patent.

### CLOSING

In view of the foregoing remarks, Applicants respectfully submit that all of the rejections or objections asserted in the Action are overcome. Accordingly, reconsideration leading to withdraw of all the rejections of claims 72-135 and 249-361 are respectfully requested. In the alternative, if any rejection or objection is again repeated, Applicants respectfully request that the Examiner withdraw the holding of finality asserted in the outstanding Action and issue another Office Action taking note of the Applicants' arguments and answering the substance of them.

If there are any remaining issues that can be addressed telephonically, the Examiner is invited to contact the undersigned to discuss the same.

Respectfully submitted,

By: 

Kevin J. Huser  
Reg. No. 56,379  
KRIEG DeVAULT LLP  
One Indiana Square  
Suite 2800  
Indianapolis, IN 46204-2079  
Tel.: (317) 636-4341  
Fax: (317) 238-6371

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